

REMARKS

In this Amendment, claims 1- 29, 35 and 46 are canceled without prejudice or disclaimer. Claim 45 is amended and claims 30-34, 36-44, and 47-64 are previously presented. It is submitted that no new matter has been added by virtue of amended claim 45, which is supported by the disclosure of the application as originally filed and by pending claim 42.

The currently pending claims are now claims 30-34, 36-45, and 47-64.

The Examiner has objected to claim 45 under 35 U.S.C. §1.75(c) as allegedly being of improper dependent form for failing to limit the subject matter of a previous claim. Claim 45 has been amended to depend from claim 31 and further specifies that the biologically active substance is a protein. Accordingly, it is respectfully requested that this objection be withdrawn.

Double Patenting

Claims 30-32, 34, 47 and 52-61 were provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 29-34, 36-41, 46 and 47 of co-pending application U.S. Serial No. 10/461,393 (hereinafter "the '393 application"). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is respectfully submitted that claims 30-32, 34, 47 and 52-61 of the instant application are not drawn to a pharmaceutically acceptable starch that is the same as that described in claims 29-34, 36-41, 46 and 47 of the '393 application. In the instant case, the pending claims are directed to a pharmaceutically acceptable starch and microparticles based on this starch, in which the starch has undergone molecular weight reduction by shearing. Claims 29-34, 36-41, 46 and 47 of the co-pending '393 application are directed to a starch in which the molecular weight of amylopectin is specifically reduced by acid hydrolysis.

The starch product claimed in the instant application and the starch product claimed in the '393 application are considered to be distinct and non-overlapping products, as the use of shearing to reduce the molecular weight of amylopectin comprising the starch results in a more narrow molecular weight distribution of the resulting starch fragments compared with acid hydrolysis. To further support the teachings of the specification in connection with the differences and distinctions between a starch product in which the molecular weight of amylopectin is reduced by shearing versus a starch product in which the molecular weight of amylopectin is reduced by acid hydrolysis, Applicants provide herewith a declaration under 37 C.F.R. §1.132 of Dr. Richard E. Jones, who is a practitioner in the design and development of pharmaceutical products and who is familiar with excipient formulations, which include starch microparticles for therapy and treatment. Dr. Jones, who is knowledgeable in the pertinent art, describes differences between a starch whose molecular weight is reduced by shearing and a starch whose molecular weight is reduced by acid hydrolysis.

In consideration of the above and the Jones declaration, Applicants submit that the present claims are not directed to the same invention as the relevant claims of the '393 application. Withdrawal of the 35 U.S.C. §101 rejection is thus respectfully requested.

Applicants acknowledge that the previously submitted terminal disclaimer, which was approved, has overcome the rejection of claims 30, 31, 36 and 42-45 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 17-19 of U.S. Patent No. 6,692,770.

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CONCLUSION

Applicants respectfully submit that the present application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**; Reference No. **28069-585 DIV**; Customer No. **35437**. Should an extension of time further to that requested herein be required in this application, the Commissioner is hereby requested to grant a petition for an extension of time such as may be required, and to change any fee(s) related thereto, to the aforementioned Deposit Account No., Reference No. and Customer No.

If the Examiner believes that further discussion of the application would be helpful, he is respectfully requested to telephone the Applicants' undersigned representative at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

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